K123566

5. 510(k) Summary

JAN 2 2 2013

Date Prepared:

January 16, 2013

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
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Device Trade Name:

Synapse 3D Colon Analysis

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Device:

- Viatronix V3D Colon, Revision 1.3 (K040126), Viatronix, Inc.

Description of the Device

Synapse 3D is medical application software running on Windows server/client configuration installed on a commercial general-purpose Windows-compatible computer. It offers software tools which can be used by trained medical professionals to aid them in reading, interpreting, reporting, and treatment planning.

Synapse 3D Colon Analysis is supporting virtual colonoscopy using CT data. Device descriptions described in this section discuss Synapse 3D Colon Analysis operating with Synapse 3D Base Tools (K120361). Some features in Synapse 3D Base Tools (K120361) are noted so the reviewer knows that Synapse 3D Base Tools (K120361) is not the focus of this submission. The device name, Synapse 3D Colon Analysis, is used in this document where necessary to specify the device of this submission.

Synapse 3D Base Tools (K120361) is connected to various DICOM compatible medical devices, such as CT, MR, CR, US, NM, PT, XA, etc. and to a PACS system storing data generated by these medical devices. It retrieves image data via network communication based on the DICOM standard and the retrieved image data are stored on the local disk managed by Synapse 3D Base Tools (K120361). The associated image-related information of the image data is registered in the database and is used for display, image processing, analysis, etc.

Synapse 3D Colon Analysis can handle images of CT. Images newly created by Synapse 3D Colon Analysis not only can be displayed on a display, but also can be printed on a hardcopy using a DICOM printer or a Windows printer.

Synapse 3D Colon Analysis with Synapse 3D Basic Tools (K120361) and above can be integrated with Synapse PACS V3.2.1 and above and with Synapse Cardiovascular system.

In summary, this 510(k) submission focuses on the Synapse 3D Colon Analysis with the capability of performing analysis on the CT images of the colon and supporting the trained medical professionals in reading, interpreting, reporting, and screening.

Indication for Use

Synapse 3D Colon Analysis is medical imaging software used with Synapse 3D Base Tools to accept, display, and process DICOM compliant 2D and 3D medical images acquired from CT for the purpose of viewing of a colon to detect polyps, masses, cancers, and other lesions. It is intended to be used by trained medical professionals in reading, interpreting, reporting, and screening.

Addition to the general 2D and 3D image processing and measurement tools available in Synapse 3D Base Tools, Synapse 3D Colon Analysis provides custom workflows, UI, and reporting functions for colon analysis, including colon segmentation, detection of the centerline of colon, fly-through of the entire colon, various rendering and visualization of colon, comparing both prone and supine views, and electronic cleansing.

Technological Characteristics

The proposed Synapse 3D Colon Analysis and the predicate device, Viatronix V3D Colon, Revision 1.3 (K040126), are medical application software running on Windows operating system installed on commercial general-purpose Windows-compatible computers. These devices are connected to CT with DICOM standard and retrieve image data via network communications. These devices provide 3D image visualization and manipulation tools for medical images with various user interfaces and measurement tools for analysis of rendered images. Both the Synapse 3D Colon Analysis and the predicate device support the workflows, UI, and reporting functions for colon analysis, including colon segmentation, detection of the centerline of colon, fly-through of the entire colon, various rendering and visualization of colon, comparing both prone and supine views, and electronic cleansing.

Synapse 3D Colon Analysis introduces no new safety or efficacy issues other than those already indentified with the predicate device. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Synapse 3D Colon Analysis is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Colon Analysis software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate device.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the performance comparison testing on retrospective images to help demonstrate that the proposed device is substantially equivalent to the predicate device.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM Medical Systems, U.S.A., Inc.
c/o Mr. Jyh-Shyan Lin
Senior Manager, Regulatory Affairs and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

January 22, 2013

Re: K123566
Trade/Device Name: Synapse 3D Colon Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 11, 2012
Received: November 20, 2012

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K123566**

Device Name: **Synapse 3D Colon Analysis**

Indications for Use:

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Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123566